

FAQ: Monoclonal Antibodies for Treatment of COVID-19

If you have recently tested positive for COVID-19 or been exposed to someone with COVID-19, then monoclonal antibody therapy may help you feel better faster and prevent the need for hospitalization from COVID-19.

What are monoclonal antibodies?

Monoclonal antibodies, or mAbs, are made in a laboratory to fight a particular infection — in this case, the virus that causes COVID-19 — and are given to patients directly with an infusion or a shot. That's why mAb treatment may help patients who are at high risk for severe symptoms or hospitalization. The Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to allow the use of monoclonal antibody therapies for the treatment of mild to moderate COVID-19 in certain high-risk patients. This treatment is not a substitute for vaccination against COVID-19.

Who is eligible for monoclonal antibody treatment?

Adults considered at high-risk for severe COVID-19 and high-risk youth ages 12-17 who weigh at least 88 pounds may be eligible for treatment. Individuals who have recently tested positive for COVID-19 and have had symptoms for 10 days or less, should talk to their health care provider to see if monoclonal antibody treatment is right for them. Some people who have been exposed to COVID-19 may qualify for treatment even before testing positive for COVID-19. If you do not have a health care provider, you can find one offering mAb treatment at 877-332-6585 or covid.infusioncenter.org.

Are monoclonal antibodies safe?

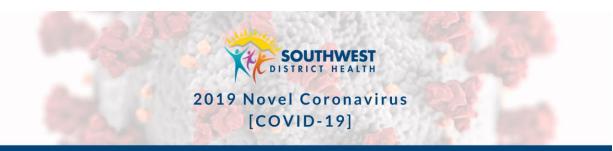
In most cases, the benefits of treatment outweigh any potential risks. While extremely rare, some severe allergic reactions have been reported with the use of monoclonal antibodies. Individuals should talk to their health care provider to see if monoclonal antibody treatment is right for them.

How much will this treatment cost?

The federal government is distributing antibody therapies at no cost to patients. However, providers may charge an administration fee for treatment. Medicare and many commercial insurance companies are covering all costs for patients. Individuals should check with their health plan to determine if they will have to bear any costs.

What are the current approved treatment options for COVID-19?

The current available therapies and links to useful resources are outlined below:



phd3.idaho.gov/covid19

- The FDA has approved the antiviral drug Veklury (remdesivir) for adults and certain pediatric patients with COVID-19 who are sick enough to need hospitalization. Veklury should only be administered in a hospital or in a health care setting.
- Monoclonal antibodies are laboratory-made molecules that act as substitute antibodies. They
 can help your immune system recognize and respond more effectively to the virus, making it
 more difficult for the virus to reproduce and cause harm. FDA has issued Emergency Use Authorization (EUA) for several monoclonal antibody treatments for COVID-19 for the treatment
 of mild or moderate COVID-19 in adults and pediatric patients ages 12 and older who are at high
 risk for progressing to severe COVID-19 and/or hospitalization.
- Post exposure prophylaxis: FDA has issued EUA for a monoclonal antibody product <u>REGEN-COV</u> for use as post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death. However, this product is not a substitute for vaccination against COVID-19.

Depending on your medical history, risks, and symptoms, your health care provider can help you determine whether a therapy that is FDA-approved, or available under an EUA, is right for you.

The following websites contain information regarding access to monoclonal antibody treatments for COVID-19:

- HHS Protect Public Data Hub Therapeutics Distribution
- National Infusion Center Association (NICA)

Therapeutic products authorized under an EUA are listed on the FDA's EUA page.

To check whether a drug is approved by FDA, search the database of approved drugs by visiting the Drugs@FDA database.

For more information:

Combatcovid.hhs.gov

Find a treatment center near you: covid.infusioncenter.org

Federal monoclonal antibody call center: For English (1-877-332-6585) or for Spanish (1-877-366-0310).